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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,107	10/10/2003	John H. Jenkins	133865	2757

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EXAMINER

RAMIREZ, JOHN FERNANDO

ART UNIT	PAPER NUMBER
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3737

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/684,107	Applicant(s) JENKINS ET AL.	
	Examiner John F. Ramirez	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application |
| 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/10/2003</u> . | 6) ☐ Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-17, 36 and 37 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

On October 26, 2005, the USPTO published Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility. See: (<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf>).

This guidelines details a procedure for determining patent eligible subject matter. As to claims 1 and 22, the first step in this process is whether the claims fall within one of enumerated categories. In the immediate application, the claims are drawn to a process - a "method for analyzing stored frames of time-stamped imaging data and time-stamped physiologic data obtained during a study of a patient during a plurality of cardiac cycles " - and meets this step. However, the analysis does not end here. The next step is whether a judicial exception (abstract ideas, laws of nature, natural phenomenon) is provided in the claim. In the immediate application, claims 1-11, and 22 clearly include one of the judicial exceptions in that "analyze the stored physiologic data to determine times of a selected phase in the plurality of cardiac cycles", the step of "select, in the plurality of cardiac cycles, stored images corresponding to the determined times of the selected phase" and the step of "align and average images

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corresponding to the selected phase across the plurality of cardiac cycles to produce a single representative frame of image data" are nothing more than abstract ideas, and claims 12-21 and 23 are directed to an apparatus including one of the judicial exceptions in that a computer configured to "analyze the stored physiologic data to determine times of a selected phase in the plurality of cardiac cycles", "select, in the plurality of cardiac cycles, stored images corresponding to the determined times of the selected phase" and "align and average images corresponding to the selected phase across the plurality of cardiac cycles to produce a single representative frame of image data" are nothing more than abstract ideas.

While abstract ideas alone are not eligible, the claim as a whole must be analyzed to determine whether it is for a particular application of the abstract idea. For claims including such excluded subject matter to be eligible, the claim must be for a practical application of the abstract idea, law of nature, or natural phenomena. To satisfy the requirement of a practical application, the claimed invention must:

(1) transform an article or physical object to a different state or thing; if no transformation, then

(2) the claimed invention must produce a useful, concrete, and tangible result.

Regarding (1) above, the claims do not provide a transformation or reduction of an article to a different state or thing. Grouping equivalent dipoles based on predetermined criterion and solving inverse problems clearly do not transform an article or physical object to a different state or thing. Accordingly, one must then consider whether the claimed invention produces a useful, concrete, and tangible result.

(1) Useful Result

For an invention to be "useful" it must satisfy the utility requirement of section 101. The USPTO's official interpretation of the utility requirement provides that the utility of the invention has to be (i) specific, (ii) substantial and (iii) credible. See MPEP 2107. It can be argued that the claim does not provide a useful result in that the claim does not actually solve a problem. It does not appear to be specific as to how the problem is solved and, if solved, it is not specific as to the use of this solution.

(2) Tangible Result

The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a 101 judicial exception, in that the process claim must set forth a practical application of that 101 judicial exception to produce a real world result.

Regarding the tangible result requirement, the claim clearly does not provide a practical application. The problem, even if solved, is not practically applied to produce a real world result. For example, once the problem is solved, how is this then applied?

(3) Concrete Result

Another consideration is whether the invention produces a "concrete" result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Resolving this question is dependent on the level of skill in the art. For example, if the claimed invention is for a process which

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requires a particular skill, to determine whether the process is substantially repeatable will necessarily require a determination of the level of skill of the ordinary skilled artisan.

Regarding the concrete result requirement, the claims do not provide a result that can be assured in that the result can not be substantially repeatable and the process can not substantially produce the same result again.

In view of the above analysis, applicant's claims 1 and 22 are a process which includes a judicial exception therein. Upon review of the claim as a whole, there is no transformation nor does the claim produce a useful, concrete, and tangible result.

Accordingly, the claims are non-statutory.

In relation to claims 2-11 depend from claim 1, and as such, include the various steps thereof. As discussed above, claim 1 is a method that provides no physical transformation and there is no practical application, which is useful, concrete and tangible.

In relation to claims 12-21 and 23 are an apparatus which includes a judicial exception therein. Upon review of the claim as a whole, there is no transformation nor does the claim produce a useful, concrete, and tangible result. Accordingly, the claims are non-statutory.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 12, 22 and 23, it is unclear as to how is determine the times of a selected phase in the plurality of cardiac cycles, Therefore, it is also unclear as to how is align and average images corresponding to the selected phase across the plurality of cardiac cycles to produce a single frame of image data.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 1, 8-12, and 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by J. Christiaens et al. *"ECG-Based Selection of Angiographic Images using DICOM Facilities"*.

J. Christiaens et al. discloses a method for analyzing stored frames of time-stamped x- ray imaging data and time-stamped physiologic data obtained during a study of a patient during a plurality of cardiac cycles, said imaging data comprising, data enhanced by injection of a contrast agent into the cardiovascular system of the patient; frames representative of a succession of images of the patient's heart; said method comprising utilizing a computer to: analyze the stored physiologic data to determine times of a selected phase in the plurality of cardiac cycles; select, in the plurality of

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cardiac cycles, stored images corresponding to the determined times of the selected phase; and align and average images corresponding to the selected phase across the plurality of cardiac cycles to produce a single representative frame of image data, wherein the physiologic data comprises ECG waveform data (see abstract, see sections: Introduction, R-peak detection, the selection of the images, the display of the selected images).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-7, and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over J. Christiaens et al. *"ECG-Based Selection of Angiographic Images using DICOM Facilities"* in view of Manning et al. (US 6,501, 979), Ossmann et al. (US 2004/0092816).

J. Christiaens et al. discloses a method for analyzing stored frames of time-stamped imaging data and time-stamped physiologic data obtained during a study of a patient during a plurality of cardiac cycles, except for mentioning specifically the steps of determining both a systolic volume and a diastolic volume, and determining an ejection fraction. However, a method for analyzing time-stamped physiologic data obtained during a plurality of cardiac cycles utilizing a computer to filter non-left ventricle anatomy

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from the single representative frame of image data, to detect edges of a left ventricle wall in the filtered, to determine both a systolic volume and a diastolic volume, and determining an ejection fraction, are conventional in the art as evidenced by the teachings of Manning et al. (US 6,501, 979), Ossmann et al. (US 2004/0092816).

Based on the above observations, for a person of ordinary skill in the art, modifying J. Christiaens et al. with a computer to filter non-left ventricle anatomy from the single representative frame of image data, to detect edges of a left ventricle wall in the filtered, to determine both a systolic volume and a diastolic volume, and determining an ejection fraction, would have been considered obvious in view of the proven conventionality of these enhancements.

With respect to claims 2 and 3, J. Christiaens et al. discloses a complete recording session of an angiographic sequence including images of the left ventricle in which each angiographic sequence contains an image sequence and a simultaneously recorded ECG sequence. In this way, the sequences and ECG signals are filtered to detect R-peaks during the recording of the sequence for display (see figures 2, 6, 7 and related description). Therefore, it would have been obvious to one having an ordinary skill in the art at the time of the invention was made to apply the above enhancements to J. Christiaens' method to derive the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John F. Ramirez whose telephone number is (571) 272-8685. The examiner can normally be reached on (Mon-Fri) 7:30 - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JFR


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